510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with requirements of 21 CFR Part 807.92.

Date: February 4, 2011

1. Company:
   Name – Guilin Woodpecker Medical Instrument Co., Ltd.
   Address – Information Industrial Park, Guilin National High-Tech Zone District, Guilin, Guangxi, 541004, P.R. China
   Telephone – +86-773-5855340
   Fax – +86-733-5855351
   Contact – Mr. Wu Xunxian
   Email – woodpeckera@mailgl.cn

   Correspondent:
   Name- IRC
   Address- 77325 Joyce Way, Echo, Oregon 97826
   Telephone- 931-625-4938
   Fax- 541-376-5063
   Contact- Charlie Mack
   Email- charliemack@irc-us.com

2. Device:
   Trade/proprietary name: Piezo Bone Surgery, Model Ultrasurgery
   Common Name : Drill, bone, powered
   Classification Name : Bone cutting instrument and accessories

3. Predicate Devices:
   MECTRON, Piezo Bone Surgery, Piezosurgery, K091227
4. Classifications Names & Citations:
   21CFR 872.4120, DZI, Drill, Bone, Powered, Class2

Description:
5.1 General
   The Guilin Woodpecker Medical Instrument Co., Ltd. Piezo Bone Surgery device is a dental device used in oral surgery situations. In this submission, it is intended to be used for bone cutting in oral surgery, removing supra and sub-gingival calculus deposits, stains from teeth, periodontal pocket lavage with simultaneous ultrasonic tip movement, scaling, root planning, and retrograde preparation of root canals.

   The device is a hand held ultrasonic surgical device, which is connected via a cord to the control console. The device operates at frequency range of 24 to 29.5 kHz. There are three modes of operation, which are selectable from the control console. The practitioner can select the Bone, Root or Clean modes of operation. Each mode has a different power mode, with the Bone mode giving the most power. Irrigation to the tip is provided and adjustable via the control console. Water flow for the irrigation is provided via a peristaltic pump.

   A selection of tips is available for the dental professional to select and use for the specific dental procedure. The available tips are shown in the User's manual and also in the advertisement brochure.

   This device is not delivered sterile, but must be sterilized after each use. Instructions for cleaning and sterilization are provided within the User's Manual.

5. Indication for use:
   The Piezo Bone Surgery is intended for use in the following dental applications:
   - Bone cutting for use in oral surgery
   - Removing supra and sub-gingival calculus deposits and stains from teeth
   - Periodontal pocket lavage with simultaneous ultrasonic tip movement
- Scaling and root planning
- Retrograde preparation of root canals

6. Comparison with predicate device:
   Guilin Woodpecker Medical Instrument Co., Ltd. believes that the Piezo Bone Surgery device, model Ultrasurgery is substantially equivalent to the Mectron, Piezosurgery® (K091227).
   Please see the next two pages for a comprehensive comparison with the predicate device.
<table>
<thead>
<tr>
<th>Element of comparison</th>
<th>Subject Device</th>
<th>Claimed SE Device</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Manufacturer</strong></td>
<td>WOODPECKER</td>
<td>MECTRON</td>
</tr>
<tr>
<td><strong>Device name</strong></td>
<td>Piezo Bone Surgery</td>
<td>Piezo Bone Surgery</td>
</tr>
<tr>
<td><strong>Device model</strong></td>
<td>Ultrasound</td>
<td>Piezosurgery Φ</td>
</tr>
<tr>
<td><strong>FDA510(K) No.</strong></td>
<td>N/A</td>
<td>K091227</td>
</tr>
<tr>
<td><strong>Intended use(s)</strong></td>
<td>The Piezo Bone Surgery is intended for use in the following dental applications:</td>
<td>The Piezosurgery 3 is intended for use in the following dental applications:</td>
</tr>
<tr>
<td></td>
<td>- Bone cutting for use in oral surgery</td>
<td>- Bone cutting for use in oral surgery</td>
</tr>
<tr>
<td></td>
<td>- Removing supra and subgingival calculus deposits and stains from teeth</td>
<td>- Removing supra and subgingival calculus deposits and stains from teeth</td>
</tr>
<tr>
<td></td>
<td>- Periodontal pocket lavage with simultaneous ultrasonic tip movement</td>
<td>- Periodontal pocket lavage with simultaneous ultrasonic tip movement</td>
</tr>
<tr>
<td></td>
<td>- Scaling and root planning</td>
<td>- Scaling and root planning</td>
</tr>
<tr>
<td></td>
<td>- Retrograde preparation of root canals</td>
<td>- Retrograde preparation of root canals</td>
</tr>
<tr>
<td><strong>Operation</strong></td>
<td>Using piezoelectric ultrasonic technology to generate mechanical micro vibrations for bone cutting and ultrasonic scaling, with minimal trauma to soft tissue.</td>
<td>Using piezoelectric ultrasonic technology to generate mechanical micro vibrations for bone cutting and ultrasonic scaling, with minimal trauma to soft tissue.</td>
</tr>
<tr>
<td><strong>Medium used</strong></td>
<td>Purified water or normal saline</td>
<td>Purified water or normal saline</td>
</tr>
<tr>
<td><strong>Tip material</strong></td>
<td>Stainless steel</td>
<td>Stainless steel</td>
</tr>
<tr>
<td><strong>Ultrasonic vibration style</strong></td>
<td>Piezoelectric Wafer</td>
<td>Piezoelectric Wafer</td>
</tr>
<tr>
<td><strong>Device for intermittent operation</strong></td>
<td>Intermittent Operation 60° ON 10° OFF</td>
<td>Intermittent Operation 60° ON 30° OFF</td>
</tr>
<tr>
<td><strong>Working frequency</strong></td>
<td>24KHz～29.5 KHz</td>
<td>From 24 KHz to 36 KHz</td>
</tr>
<tr>
<td><strong>Voltage supply</strong></td>
<td>100-120VAC 50/60Hz</td>
<td>100-240 VAC 50/60 Hz</td>
</tr>
<tr>
<td><strong>APC circuit protection systems</strong></td>
<td>No hand piece connected</td>
<td>No hand piece connected</td>
</tr>
<tr>
<td></td>
<td>Cord interrupted</td>
<td>Cord interrupted</td>
</tr>
<tr>
<td></td>
<td>Insert broken or not correctly tightened</td>
<td>Insert broken or not correctly tightened</td>
</tr>
<tr>
<td><strong>Power Modes</strong></td>
<td>ROOT mode</td>
<td>ROOT mode</td>
</tr>
<tr>
<td></td>
<td>BONE mode</td>
<td>BONE mode</td>
</tr>
<tr>
<td></td>
<td>IMPL mode</td>
<td>IMPL mode</td>
</tr>
<tr>
<td><strong>IEC60601-1 Class</strong></td>
<td>Type B Class I</td>
<td>Type B Class I</td>
</tr>
</tbody>
</table>

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桂林市啄木鸟医疗器械有限公司
GUANG WOODPECKER Medical Instrument Co., LTD.
<table>
<thead>
<tr>
<th><strong>Device classification using Directive 93/42EEC</strong></th>
<th>Class IIa</th>
<th>Class II a</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Peristaltic pump volume delivery</strong></td>
<td>From 25 to 100 ml / min approx</td>
<td>From 0 to 90 ml / min approx</td>
</tr>
<tr>
<td><strong>Fuses</strong></td>
<td>Type 5 x 20 mm 2×T1.0AL 250V</td>
<td>Type 5 x 20 mm 230 VAC 2 X 2 A T</td>
</tr>
<tr>
<td><strong>Environmental operating conditions</strong></td>
<td>from +10°C to +40°C Relative humidity from 30% to 70%</td>
<td>from +10°C to +40°C Relative humidity from 30% to 75%</td>
</tr>
<tr>
<td><strong>Transport and storage environmental conditions</strong></td>
<td>from -10°C to +50°C Relative humidity from 10% to 90%. Air pressure P: 500hPa/1060hPa</td>
<td>from -10°C to +70°C Relative humidity from 10% to 90%. Air pressure P: 500hPa/1060hPa</td>
</tr>
<tr>
<td><strong>Where used</strong></td>
<td>Oral surgery Implantology Periodontal surgery Surgical orthodontics</td>
<td>Oral surgery Implantology Periodontal surgery Surgical orthodontics</td>
</tr>
<tr>
<td><strong>Biocompatibility</strong></td>
<td>Complying with ISO10993-1</td>
<td>Complying with ISO10993-1</td>
</tr>
<tr>
<td><strong>Weight and Size</strong></td>
<td>3.8KG L x W x H:333 x 255 x 167mm</td>
<td>3.2 Kg L x W x H:340 x 210 x 150 mm</td>
</tr>
<tr>
<td><strong>Clean and disinfection method</strong></td>
<td>Clean and disinfect the surfaces of the casing, the cords and their connectors using a cloth moistened with a mild detergent or disinfectant solution with a neutral pH (pH 7).</td>
<td>Clean and disinfect the surfaces of the casing, the rod, the hand piece-holder, the cords and their connectors using a low fiber release cloth moistened with a detergent solution (pH 6-9) and/or a mild disinfectant with a neutral pH (pH7)</td>
</tr>
<tr>
<td><strong>Sterilization method</strong></td>
<td>Maximum temperature of 135°C for a maximum of 20 minutes.</td>
<td>Maximum temperature of 135°C for a maximum of 20 minutes.</td>
</tr>
<tr>
<td><strong>Components can be sterilized</strong></td>
<td>Hand piece, Tips, Tip holder, Torque wrench, Pump tube, Cord/peristaltic pump tube connection, Hand piece holder</td>
<td>Hand piece, Inserts, Wrench for tightening the inserts, Tube for the peristaltic pump, Connection for the cord / tube of the peristaltic pump, Rod for supporting the bag, Support for the hand piece</td>
</tr>
</tbody>
</table>
7. Safety and Performance Data:

 Electrical, mechanical, environmental safety and performance testing according to EN/IEC 60601-1[1990] Medical electrical equipment
 Performance testing was used to validate the effectiveness and accuracy of the device. All test results were satisfactory.

9. Conclusions:

 In accordance with the Federal Food, Drug and Cosmetic Act, 21 CFR Part 807 and based on the information provided in this premarket notification Guilin Woodpecker Medical Instrument Co., Ltd. concludes that the Piezo Bone Surgery device, model Ultrasurgery is substantially equivalent to predicate devices as described herein.

END
Guilin Woodpacker Medical Instrument Company, Limited  
C/O Mr. Charlie Mack  
Principal Engineer  
International Regulatory Consultants  
77325 Joyce Way  
Echo, Oregon 97826

Re: K111290

Trade/Device Name: Piezo Bone Surgery  
Regulation Number: 21 CFR 872.4120  
Regulation Name: Bone Cutting Instrument and Accessories  
Regulatory Class: II  
Product Code: DZI, ELC  
Dated: November 6, 2011  
Received: November 9, 2011

Dear Mr. Mack:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

[Signature]

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure
Indications for Use

510(k) Number (if known): K111290

Device Name: Piezo Bone Surgery

Indications For Use:

The Piezo Bone Surgery is intended for use in the following dental applications:

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- Scaling and root planning
- Retrograde preparation of root canals

Prescription Use ✔ AND/OR Over-The-Counter Use ______
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(Please do not write below this line—continue on another page if needed)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K111290